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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/712,122

11/13/2003

John D. Pluenneke

3369-A

7679

22932 7590 10/12/2005

IMMUNEX CORPORATION  
LAW DEPARTMENT  
1201 AMGEN COURT WEST  
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EXAMINER

DELACROIX MUIRHEI, CYBILLE

ART UNIT

PAPER NUMBER

1614

DATE MAILED: 10/12/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

Application No.

10/712,122

Applicant(s)

PLUENNEKE, JOHN D.

Examiner

Cybille Delacroix-Muirheid

Art Unit

1614

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☐ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-7 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_ is/are allowed.
- 6) ☐ Claim(s) \_\_\_\_ is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_ is/are objected to.
- 8) ☒ Claim(s) 1-7 are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. ____. |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date ____. | 6) <input type="checkbox"/> Other: ____.  |

## DETAILED ACTION

### *Election/Restrictions*

Restriction to one of the following inventions is required under 35 U.S.C. 121:

- I. Claims 1-2, drawn to a method for reducing tumor burden, classified in class 514, subclass 2+.
- II. Claims 3-4, drawn to a method for inhibiting recurrence of gross cystic disease of the breast, classified in class 514, subclass 2+.
- III. Claims 5-7, drawn to a method for preventing or reducing the frequency or severity of transient ischemic attacks or strokes, classified in class 514, subclass 2+.

The inventions are distinct, each from the other because of the following reasons:

The invention of Group I is directed to a method of reducing tumor burden in a human patient; the invention of Group II is directed to a method of inhibiting the recurrence of gross cystic disease of the breast; the invention of Group III is directed to a method of preventing or reducing the frequency or severity of transient ischemic attacks or strokes. Each method has a separate and distinct outcome from the expected outcome of any one or more of the other methods. For example, the expected result of a method of treating tumor burden is distinctly different from a method of reducing the frequency or severity of ischemic attacks strokes, since the desired outcome of reducing tumor burden is to arrest abnormal proliferation and metastatic spread of tumor cells, whereas the desired outcome of treating ischemic attacks or strokes is to reduce the likelihood of an ischemic attack in a patient suffering from, for example,

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hypertension.

Additionally, each of the methods would be practiced in a distinctly different population of patients. While there may be incidental overlap in the groups of patients experiencing, for example, cancer and those experiencing, for example, strokes or gross cystic disease of the breast, the therapeutic objective, endpoints and steps required to treat such dissimilar conditions are vastly different and do not reasonably suggest the treatment of the other. Finally, the search for one Group would not be required for the other. For these reasons, the inventions of Groups I-III are considered to be independent and distinct and restriction for examination purposes is proper.

A telephone call was made to Applicant's representative on March 21, 2005 to request an oral election to the above restriction requirement, but did not result in an election being made.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to **Cybill Delacroix-Muirheid** whose telephone number is **571-272-0572**. The examiner can normally be reached on Mon-Thurs. from 8:30 to 6:00 as well as every other Friday from 9:30-6:00.


If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, **Christopher Low**, can be reached on **571-272-0951**. The fax phone number for the organization where this application or proceeding is assigned is **571-273-8300**.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

CDM

Oct. 6, 2005

  
Cybille Delacroix-Muirheid  
Patent Examiner Group 1600